

REMARKS

This is in response to the Official Action mailed December 16, 2003. Applicant requests a one-month extension of time to respond, and payment of the \$110 extension fee is enclosed herewith. If any additional fees are required, the Assistant Commissioner is authorized to charge the same to the account of Barnes & Thornburg, Deposit Account No. 10-0435, with reference to our matter number 5727-71312.

Rejection of Claim 26-28 Under 35 U.S.C. § 102(b)

The Examiner has rejected claims 26-28 under 35 U.S.C. § 102(b) as being anticipated by Reidel (U.S. Patent No. 5,801,817). In particular, on page 2, the Examiner states the following:

The reference shows a method for analyzing sample liquids comprising evaluating test elements using an analytical unit. There is a position control unit is used to check whether an analytical area of the test element is positioned correctly (*i.e.*, in or out of the "nominal position") relative to the analytical unit. The system works by irradiating an area of the test element (12) by a light source (14), detecting radiation reflected from the area (by detectors 32, 34 in figures 3 and 5), and recording (in the circuit of figure 5) a signal (the "correction signal") generated by the detecting step to check the position (in or out of the "nominal position") of the analytical area wherein the light source and detector are positioned relative to one another in such a manner that the intensity of radiation reflected from the test element and detected is different when the analytical area is correctly positioned (in the "nominal position") than the intensity when it is incorrectly positioned (out of the nominal position); as set forth in the reference, the "position control unit" operates by the fact that the intensity varies as the position of the test strip varies (column 5, lines 14 *et seqq.*).

The analytical unit which produced the measurement as used produced the actual useful measurement at some time less than one second after the position control unit begins to determine the location of the sample; the feedback arrangement to correct the reading based upon the position will be rapid but not instantaneous.

The Applicant respectfully traverses the subject rejection and requests that it be withdrawn in light of the following discussion.

Discussion of Claim 26

As indicated above claim 26, as amended, reads as follows:

26. A method for analyzing sample liquids comprising evaluating test elements using an analytical unit in which a position control unit is used to check whether an

analytical area of the test element is positioned correctly relative to the analytical unit, irradiating an area of the test element by a light source, detecting radiation reflected from the area, recording a signal generated by the detecting step to check the position of the analytical area wherein the light source and detector are positioned relative to one another in such a manner that the intensity of radiation reflected from the test element and detected is different when the analytical area is correctly positioned than the intensity when it is incorrectly positioned, and indicating to a user whether the analytical area is positioned correctly relative to the analytical unit.

The Applicant respectfully points out to the Examiner that Riedel does not teach each and every element of claim 26. For example, Riedel does not teach a method for analyzing sample liquids that includes indicating to a user whether an analytical area is positioned correctly relative to an analytical unit. In particular, Riedel is directed to a method and apparatus for **eliminating** the effects of varying sample distance on optical measurements. In particular, Riedel states the following with respect to the method and apparatus described in U.S. Patent 5,801,817:

The present invention utilizes two distinct techniques for providing an optical reflectance measurement value which is independent of the distance between the light source and the measurement sample and the distance between the light detector and the measurement sample. (See Col. 3, lines 37-41)

The measurement system 10 works by using the self-compensating effects of the lensing system 18, 20. If the measurement sample 12 moves closer to the source 14/detector 16 system, then the light intensity hitting the measurement sample 12 from the source 14 is smaller because the measurement sample 12 is now farther away from the focal plane of the source 14 (coinciding with the focal point S). However, because the detector 16 focal point D lies in front of the measurement sample 12, the light flux hitting the detector 16 is now larger. This is because the measurement sample 12 has moved closer to the focal plane of the lens 20 (coinciding with the focal point D). With the measurement system 10 of FIG. 1, the lensing effects of the source and the detector cancel each other out, thereby eliminating any measurement error associated with varying the sample distance D. It will be appreciated by those skilled in the art that movement of the measurement sample 12 in the opposite direction (increasing sample distance d) results in the same canceling effect. Furthermore, it will be appreciated by those skilled in the art that placing the focal point S in front of the measurement sample 12 and placing the focal point D behind the measurement sample 12 also provides the same effect. (See Col. 4, lines 10-33)

Accordingly, the Examiner will appreciate that, since Riedel does not teach a method for analyzing sample liquids that includes indicating to a user whether an analytical area is positioned correctly relative to an analytical unit, this reference does not teach each and every element of claim 26. As such, Riedel does not anticipate claim 26 and the Applicant respectfully requests that the subject rejection be withdrawn.

Discussion of Claims 27 and 28

Each of claims 27 and 28 include claim 26 as a base claim. Therefore, each of these claims include the same limitations recited in claim 26. Accordingly, the discussion with respect to claim 26 is applicable to claims 27 and 28, and the Applicant respectfully requests that the subject rejection of these claims also be withdrawn.

Rejection of Claims 15-25 Under 35 U.S.C. § 103(a)

Claims 15-25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Riedel (U.S. Patent No. 5,801,817) as applied to claim 26, and further in view of Backhaus et al. (U.S. Patent No. 5,605,838). In particular, on page 3, the Examiner states the following:

Riedel shows a system such as is claimed, determining whether or not the test strip is or is not in the correct (“nominal”) position, based upon the detected intensity of light from the test strip. See above. Riedel does not teach using specularly reflected light as in independent claim 15. It is known in the art that optical tests on test strips and the like can be made with specularly reflected light; see Backhaus et al. (“Light that is diffusely or specularly reflected from the sample and sample carrier is detected and analysed”; abstract, lines 3-5). It would have been obvious to use specularly reflected light from the sample in this known manner as the light detected by one of the detectors in the device of Reidel because it is a known arrangement which will produce the same type of response as the scattered light of Reidel. The exact arrangement of the light source and detectors of Reidel can be modified by those in the art because it is the difference in the response of the two detectors based upon the difference in distance that gives the disclosed useful result and the art does not teach or suggest that an exact relationship is necessary.

Jina et al., in figure 13, shows using light reflected from the test strip when it is in the correct position to determine whether a test strip is in the correct position for measurement or not based upon a difference between the reflected light from the test element when the test element is correctly positioned and the reflected light when it is incorrectly positioned.

The Applicant respectfully traverses the subject rejection and requests that it be withdrawn in light of the following discussion.

Discussion of Claim 15

Claim 15 reads as follows:

15. A system for analyzing sample liquids by evaluating test elements with an analytical unit in which a test element to be analyzed is positioned by a holder in an analytical position relative to the analytical unit and the system additionally comprises a position control unit to check whether an analytical area of the test element is correctly positioned relative to the analytical unit wherein the position control unit comprises:

- (a) a light source to irradiate an area of the test element,
- (b) a detector to detect light reflected from the area, and
- (c) an evaluation unit, wherein the light source and detector are positioned relative to one another in such a manner that the light intensity of specularly reflected radiation at the detector when the test element is correctly positioned is different from a light intensity when it is incorrectly positioned and the evaluation unit is adapted to recognize any faulty positioning on the basis of the light intensity of the detector.

The Examiner acknowledges that that Riedel does not teach using specularly reflected light as recited in independent claim 15. In an attempt to cure this deficiency the Examiner relies upon Backhaus et al. and argues that “[i]t would have been obvious to use specularly reflected light from the sample in this known manner as the light detected by one of the detectors in the device of Reidel because it is a known arrangement which will produce the same type of response as the scattered light of Reidel.” In response the Applicant respectfully points out that in order to establish a proper prima facie case of obviousness the Examiner must provide some reason, suggestion, or motivation from the prior art as a whole for the person of ordinary skill to have combined or modified the relied upon references. In other words the Examiner must set forth some reason, suggestion, or motivation from the prior art as to why an artisan would combine Reidel with Backhaus et al.¹ In an attempt to do so, as indicated above, the Examiner argues that using specularly reflected light would produce the same type of response as the scattered light. Therefore, it appears that the Examiner’s argument to support the subject obvious rejection is that specularly reflected light would produce the same type of response as the scattered light, and therefore an artisan

¹ Note that the Applicant is not conceding that the proposed Reidel/Backhaus et al combination arrives at the invention of claim 15.

would be motivated to modify Reidel to utilize specularly reflected light as opposed to scattered light.

Applicant respectfully disagrees that the argument and reasoning the Examiner relies upon satisfies the requirement that one must provide some reason, suggestion, or motivation from the prior art as a whole for the person of ordinary skill to have combined or modified the relied upon references. For example, the Examiner states that specularly reflected light would produce the same type of response as the scattered light. If this is the case, i.e. specularly reflected light produces the same type of response as the scattered light, then why would an artisan be motivated to modify Reidel to use specularly reflected light in place of scattered light ? The Applicant reminds the Examiner that the mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. Reidel and Backhaus et al. fail to suggest any motivation for, or desirability of, the changes espoused by the Examiner.

Furthermore, the Applicant respectfully submits that the Examiner has relied upon hindsight to arrive at the determination of obviousness. The Applicant reminds the Examiner that it is impermissible to use the claimed invention as an instruction manual or “template” to piece together the teachings of the prior art in an attempt to render the invention obvious. The Federal Circuit has previously stated that “[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.” (see *In re Fritch*, 972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992)). Accordingly, an Examiner cannot simply cite different features of the claimed invention from different prior art sources without providing a satisfactory explanation as to the motivation to combine or modify the prior art references.

In light of the above discussion, Applicant submits that the Examiner has **not** provided some reason, suggestion, or motivation from the prior art as a whole for the person of ordinary skill to have combined or modified the relied upon references. As such, the Examiner has not established a proper *prima facie* case obviousness, and the Applicant respectfully requests that the subject rejection be withdrawn.

Discussion of Claims 16-25

Each of claims 16-25 include claim 15 as a base claim. Accordingly, the above discussion with respect to claim 15 is applicable to each of claims 16-25, and the Applicant respectfully requests that the subject rejection of these claims also be withdrawn.

Furthermore, each of claims 16-25 include novel and nonobvious limitations in addition to those recited in independent claim 15. Therefore, if after considering the above discussion the Examiner maintains the subject rejection, the Applicant respectfully requests the Examiner to point out with particularity (i.e. by column and line number) where each element of the rejected claim is taught or suggested by the relied upon references. Merely stating that the "exact arrangement of the light source and detectors of Reidel can be modified by those in the art because . . . the art does not teach or suggest that an exact relationship is necessary" does not fulfill the requirements for establishing a proper prima facie case of obviousness.

CONCLUSION

In view of the foregoing remarks, it is submitted that this application is in condition for allowance. Action to that end is hereby solicited.

In the event that there are any questions related to this response in particular, or to the application in general, the undersigned would appreciate the opportunity to address those questions directly in a telephone interview to expedite the prosecution of this application for all concerned.

In conclusion, should any additional fees be required to render this response timely, or in the event of overpayment, the Commissioner is hereby authorized to charge or credit Applicant's undersigned counsel's Deposit Account 10-0435, with reference to our file 5727-71312. A duplicate copy of this authorization is enclosed for that purpose.

Respectfully submitted



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